

# Certificate of Registration

**Certificate number**

3414.260204

**File number**

A28936

**Initial issue date**

2022-03-08

**Cycle start date**

2025-03-08

**Effective date**

2026-02-04

**Expiry date**

2028-03-07

**Sunset Healthcare Solutions**2725 Alft Lane  
Elgin, Illinois 60124 UNITED STATES

Facility ID: F005491

UL LLC, UL Solutions medical and regulatory services issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in conformance per the defined scope with respect to:

**ISO 13485:2016**  
**EN ISO 13485:2016/A11:2021**

with additional regulatory requirements listed on the final page of this certificate.

Design and manufacturing of respiratory filters;

The contract manufacturing and distribution of Continuous Positive Airway Pressure (CPAP) masks, tubing, handheld compressor nebulizers, nasal pillow CPAP masks, and CPAP cleaners;

Certificate with Addendum(s) totals 3 pages.

Authorized by:

A handwritten signature in black ink, appearing to read 'P. Daysh'.

Paul Daysh  
Operations manager – Medical Regulatory



Check certificate status: [here](#)

This quality system registration is included in UL's Product IQ directory and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown. By issuance of this certificate, the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferrable and remains the property of UL Solutions.

**UL LLC, UL Solutions medical regulatory services**  
**is an MDSAP Recognized Auditing Organization**

UL LLC  
333 Pflingsten Road  
Northbrook, IL 60062-2096 USA

# Addendum 1

Site	Company Name	Location	Performing
1-1	Sunset Healthcare Solutions	141 West Jackson Boulevard Suite 1950 Chicago Illinois 60604 UNITED STATES Facility ID: <b>F005491</b>	Corporate headquarters, accounting, sales, customer service.
2-1	Sunset Healthcare Solutions	2725 Alft Lane Elgin Illinois 60124 UNITED STATES Facility ID: <b>F005898</b>	Design, manufacturing, repackaging, relabeling, distribution.
3-1	Sunset Healthcare Solutions	6750 W. Van Buren St. STE 100 Phoenix Arizona 85403 UNITED STATES Facility ID: <b>F006820</b>	Receiving, Repacking, Labeling, Distribution

# Additional Regulatory Requirements

## Sunset Healthcare Solutions

2725 Alft Lane  
Elgin, Illinois 60124 UNITED STATES

Facility ID: F005491

### Brazil:

- RDC ANVISA n. 665/2022
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009

### Canada:

- Medical Devices Regulations – Part 1- SOR 98/282

### Japan:

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act (,as applicable)

### United States:

- 21 CFR 820
- 21 CFR 803
- 21 CFR 806
- 21 CFR 807 – Subparts A to D
- 21 CFR 821 (where applicable)